

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number NDA 21-108

MICROBIOLOGY REVIEW(S)

REVIEW FOR HFD-540

JAN 13 2000

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review # 2 of NDA 21-108

January 11, 2000

- A. 1. APPLICATION NUMBER: NDA 21-108
- APPLICANT: Johnson & Johnson
199 Grandview Road
Skillman, NJ 08558
(tel) 908-874-1239
(fax) 908-874-1118
2. PRODUCT NAME: Renova®
3. DOSAGE FORM: Tretinoin (0.02%) cream supplied in — 40 g, and —
— tubes and as Physician's Samples.
4. METHOD OF STERILIZATION: None (non-sterile product).
5. PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:
Adjunctive agent for use in the mitigation of fine wrinkles, mottled
hyperpigmentation, and tactile roughness of facial skin.
- B. 1. DATE OF INITIAL SUBMISSION: 8/31/99
2. DATE OF AMENDMENT: 12/16/99
3. DATE OF CONSULT: 12/20/99
4. ASSIGNED FOR REVIEW: 01/07/00
5. RELATED DOCUMENTS: NDA 19-963 (Tretinoin emollient cream 0.05%)
- C. REMARKS: Microbiologist's Review #1 (dated 11/10/99) yielded two deficiencies
which were faxed to the applicant on 12/10/99. The applicants response to these
deficiencies is the subject of this review (Microbiologist's Review #2).

APPEARS THIS WAY
ON ORIGINAL

D. CONCLUSIONS:

The application recommended for approval of issues concerning microbial limits and preservative effectiveness testing of the drug product. Specific comments are provided in section "E. REVIEW NOTES".

[/S/] 1/11/00
Neal Sweeney, Ph.D.
[/S/] 1/13/00

cc:

Original NDA 21-108
HFD-540/Division File
HFD-540/CSO/O. Cintron
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, January 11, 2000
R/D initialed by P. Cooney, January 11, 2000

**APPEARS THIS WAY
ON ORIGINAL**

WITHHOLD 1 PAGE (S)

REVIEW FOR HFD-540

NOV 22 1999

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review # 1 of NDA 21-108

November 10, 1999

- A. 1. APPLICATION NUMBER: NDA 21-108
- APPLICANT: Johnson & Johnson
199 Grandview Road
Skillman, NJ 08558
(tel) 908-874-1239
(fax) 908-874-1118
2. PRODUCT NAME: Renova®
3. DOSAGE FORM: Tretinoin (0.02%) cream supplied in _____ 40 g. _____
_____ and as Physician's Samples.
4. METHOD OF STERILIZATION: None (non-sterile product).
5. PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:
Adjunctive agent for use in the mitigation of fine wrinkles, mottled
hyperpigmentation, and tactile roughness of facial skin.
- B. 1. DATE OF INITIAL SUBMISSION: 8/31/99
2. DATE OF CONSULT: 9/3/99
3. ASSIGNED FOR REVIEW: 9/22/99
4. RELATED DOCUMENTS: NDA 19-963 (Tretinoin emollient cream 0.05%)
- C. REMARKS: Volumes 1.1 (application Summary), 1.2 (Application Summary), and
1.17 (Microbiology) were provided for consult review.

APPEARS THIS WAY
ON ORIGINAL

D. CONCLUSIONS:

The application is approvable pending resolution of issues concerning microbial limits and preservative effectiveness testing of the drug product. Specific comments are provided in sections "E. REVIEW NOTES" and "List of Microbiology Deficiencies and Comments".

[/S/] 11/10/99
Neal Sweeney, Ph.D.
[/S/] 11/22/99

cc:

Original NDA 21-108
HFD-540/Division File
HFD-540/CSO/O. Cintron
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, November 10, 1999
R/D initialed by P. Cooney, November 10, 1999

APPEARS THIS WAY
ON ORIGINAL

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